

REMARKS

1. Applicant appreciates the Examiner's reconsideration of this application.
2. Claims 49-64 are pending in the application.

Response to Rejections Under 35 U.S.C. 112, first and Second Paragraphs

3. The Office Action mailed May 4, 2006 rejected Claims 49-64 under 35 U.S.C. 112, first and second paragraphs.

4. In this Response to the Office Action mailed May 4, 2006, Applicant is now amending Claims 49, 51, 60, and 63 to return all the Claims 49-64 to the exact language of these claims that was on appeal as shown in the Corrected Brief for Appellants, Appendix A, filed by express mail on January 27, 2003.

5. In brief explanation, Applicant did not intend to amend the claims from the claims as they stood during the previous appeal. In the long prosecution of this case, it appears an earlier set of the claims or a draft set of the claims was inadvertently presented after the appeal, rather than the intended set of claims as they stood during the appeal. Applicant notes that, when represented on January 17, 2006 (and in response to a notice of non-compliance, again on February 14, 2006), all the claims indicated that they were "previously presented" without amendment, and the remarks sections did not indicate that any amendments were intended.

6. The Examiner noted one of the inadvertent "amendments" in the Office Action mailed May 4, 2006 and rejected the claims.

7. By filing a request for continued examination and this amendment, the Applicant is requesting the Examiner to reconsider the claims as they were intended be presented and as they were presented during the previous appeal. No new matter has been added by this amendment.

Arguments for Patentability of Claims 49-64 as Intended to Be Presented

8. In view of the Appeal Brief filed on January 28, 2003, the Office Action dated July 15, 2005 reopened prosecution of this application. In the response filed January 17, 2006, Applicant elected to file a reply under 37 CFR 1.111 to the non-final Office Action.

9. Claims 49-64 are now pending in this application. In the interest of simplifying issues for the continued prosecution of this application, in the response filed January 17, 2006, Applicant had canceled Claims 65-66 without prejudice.

10. In the Office Action dated July 15, 2005, then pending Claims 49-64 (verbatim to the now-pending Claims 49-64) had been rejected under 35 U.S.C. 103(a) as being unpatentable over Youdim et al. in view of Warren (US Patent No. 4,435,384), Gouat et al. (US Patent 4,001,080) and Lane et al. To any extent the Examiner would reassert this rejection with respect to the pending Claims 49-64, such rejection is respectfully traversed, and reconsideration is requested.

11. To make the four-way hypothetical combination of the cited references, the rejection relies on the statements in Warren that: "Transfer factor is obtained from the lymphocytes of a donor having no history of recurrent infection by herpes virus." (Col. 2, lines 35-37); and that the process in Warren includes the step: "1. Obtain a heparinized whole blood sample from a suitable donor." (Col. 2, lines 47-50).

12. Applicants have considered the cited references, including the hypothetical combination in the Office Action dated July 15, 2005 based on the cited statements in Warren.

13. The Warren patent teaches that transfer factor is obtained from any individual who has no history of a recurrent infection, specifically herpes virus. All cases cited in the Warren patent are patients with herpes simplex or condylomatous growth, not otherwise specified. Transfer factor was prepared by removing lymphocytes from a "suitable donor" that does not have a history of recurrent infection by herpes virus. Transfer factor was obtained from these lymphocytes that have been removed from any other patient other than that one with the viral infection, i.e., an allogeneic donor, not an autologous donor. Thus,

transfer factor as taught by Warren did not have any relationship or association with autologous donation.

14. It is clear that Warren's patent taught that transfer factor was to be used topically on patients with viral infections. Warren excluded taking cells from any patient with a history of such a viral infection. Thus, a routineer cannot draw the conclusion that any source of lymphocytes can be used. The lymphocytes simply must come from any patient other than the patient being treated for such a skin infection.

15. Based on the accepted definition of "transfer factor" as being allogeneic and based on the concern for allogeneic donor issues in Warren (i.e., no history of herpes virus and concern for using "a suitable" donor), the proper understanding of the terms "donor" and "transfer factor" in Warren is solely in the context of allogeneic donation. Warren does not disclose or suggest autologous donation.

16. These remarks are supported by the declaration of Dennis G. Hooper, M.D., Ph.D., a copy of which is attached.

17. Based on the foregoing, the hypothetical combination of the four references made in the Office Action dated July 15, 2005 does not teach or suggest the invention as defined by Claims 49-64.

Conclusion

18. The pending Claims 49-64 are believed to be patentable and now in condition for allowance, and such action is respectfully requested. Applicant trusts that the Examiner will help the undersigned bring the long prosecution of this application to a favorable conclusion. If a telephone interview would help conclude any matters of form or otherwise, the undersigned would sincerely appreciate a telephone conference and can normally be reached at the office telephone number below or can normally return a call within one business day.

DATED: June 30, 2006

CERTIFICATE OF MAILING

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June 30, 2006

Respectfully submitted,



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